

**MEMORANDUM**

Via E-Mail

DATE: May 3, 2019

TO: Ethylene Oxide Sterilization Association, Inc. Members

FROM: Mr. Jake Vandevort  
B&C® Consortia Management, L.L.C.

RE: April 30, 2019, Ethylene Oxide Stakeholders Meeting

On April 30, 2019, the National Association of Manufacturers (NAM) hosted an Ethylene Oxide (EO) Stakeholder Group meeting. The purpose of this meeting was to facilitate stakeholder discussion on legislative and regulatory updates, group messaging, outreach, and next steps. Below are key points addressed during this meeting.

**Federal Matters**

- Greg Crist of the Advanced Medical Technology Association (AdvaMed) reported on concerns regarding threats posed by the shortage of EO sterilization services to sterile medical devices supplies, citing pediatric breathing tubes as one current example.
- Crist reported that recent discussions of EO sterilization in Illinois appear to be focusing more on efficiency and the use of lesser quantities of EO for sterilization. Crist noted that there seems to be a misconception that alternatives are available for immediate use.
- AdvaMed suggests that more than 50 billion medical devices are sterilized annually by EO sterilization.
- AdvaMed has arranged meetings with the U.S. Environmental Protection Agency (EPA) and staff of the U.S. Senate Committee on Environment and Public Works (EPW). Crist suggested that while specifics are not available, it is clear that EPA, the U.S. Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC) are having interagency discussions on EO.

{00606.001 / 111 / 00269180.DOCX 7}